IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
CHARLESTON DIVISION

IN RE: LIPITOR (ATORVASTATIN CALCIUM) MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION	MDL No. 2:14-mn-02502-RMG This Document Relates to All Actions

PLAINTIFFS' RESPONSE IN OPPOSITION TO PFIZER INC.'S MOTION TO STRIKE SUPPLEMENTAL REPORT OF DR. ROBERTS

Plaintiffs hereby submit the following memorandum in opposition to Pfizer's Motion to Strike Supplemental Report of Dr. Roberts. Pfizer argues that Dr. Roberts's supplemental report should be stricken due to "three independent and material deviations from CMO 49." As will be discussed below, Pfizer's objections are without merit, and its motion should be denied.

I. Dr. Roberts's Report Clearly Details Her Opinion as to Each Dosage Level.

Pfizer's first criticism takes issue with the organization and manner of presentation that Dr. Roberts chose for her report and claims that her alleged failure to "stratify by dose" warrants the striking of her entire report. This criticism is ridiculous. Dr. Roberts clearly relays her opinion that Lipitor can cause diabetes in "dosages across the range of 10 mg, 20 mg, 40 mg and 80 mg daily,"[1] This Court's Order requires only that the report "set forth the facts and data" that support the expert's opinion.[2] The Court did not require any specific organizational structure for the expert's report and certainly did not order so-called stratification by dose.

Dr. Roberts repeatedly makes clear her opinion as to each of the four dosages throughout her report. Moreover, Pfizer had ample opportunity at Dr. Roberts's deposition on December 18, 2015, to clarify any issues related to her opinions at any dosage level. Her decision not to

[1] Supplemental Report of Barbara H. Roberts, M.D. ("Report") at 1.
[2] CMO 49 at 11.

organize her report in a manner that Pfizer apparently would have preferred is not a valid reason to strike her report.

II. Dr. Roberts Reliance on the Mansi and Gastaldi Papers Was Reasonable and in No Way Prejudices Pfizer.

Pfizer's second criticism of Dr. Roberts's report is, at best, a hyper-technicality and should not serve to bar Dr. Roberts's supplemental report. Pfizer takes issue with Dr. Roberts's citations to two papers, by Mansi[3] and Gastaldi[4], that were not in her initial report nor in Plaintiffs' Response to the Court's September 28th Order.

As an initial matter, both articles were published after the disclosure of Plaintiffs' expert reports and thus could not have been included in Dr. Roberts's or any other Plaintiffs' expert's report. The Mansi study was published in April 2015, and Gastaldi was published in May 2015. Moreover, only Mansi is discussed substantively by Dr. Roberts. Gastaldi is not a study, but a commentary, and Dr. Roberts only quotes it rhetorically in the summation of her opinions.

At the Court's October 22 hearing, it was clear the Court was concerned with Pfizer's *notice* of a particular report or study that Plaintiffs' Experts might rely upon:

> If you can demonstrate to me that your expert has previously relied on something, and you can show me in a report where they did, and it's already in the record, I'm okay with that. And I will allow that. But what we're not doing is we're not sending Dr. Jewell back to do something new. 10/22/15 Hearing Tr. at 55:4-9.
>
> We're not reshuffling the deck and starting over again. But I think to the extent there is something in one of those -- they previously relied on, and you didn't mention it, *as long as the other side has seen the report and all that data has been previously disclosed*, your reliance, I don't really have a problem with that." *Id*. at 55:11-16. (emphasis added).

[3] Mansi et al., *Statins and new-onset diabetes mellitus and diabetic complications: A retrospective cohort study of US healthy adults*, 30 J. GEN. INT. MED. 1599 (2015).
[4] Gastaldi & Phillippe, *Statins and diabetes" The plot thickens*, 30 J. GEN. INT. MED. 1572 (2015).

Additionally, CMO 49 states: "An expert may only consider and rely on studies or data submitted to the Court in the response to its September 28, 2015 text order, (s*ee* Dkt. Nos. 1153, 1159), or specifically cited in an expert's prior report." Again given the timing of its publication, Mansi could not have been in Plaintiffs' experts' reports, but it was in fact used in other experts' reports served later, and was used in the depositions of several experts. For example, one of Pfizer's experts, Dr. Tom Elasy, listed the Mansi study in his materials considered for his case-specific expert report in the Daniels case. Further, Plaintiffs used Mansi as an exhibit in the depositions of four of Pfizer's experts—Drs. Hennekens, Lopes-Virella, Waikar and Fonseca. Mansi was also specifically cited by Plaintiffs' case-specific experts, Drs. Handshoe and Murphy. Thus, Pfizer cannot be heard to complain that it was unaware of the Mansi study, and Dr. Roberts should be afforded the opportunity to consider and discuss it as part of her supplemental report as it was cited in two of Plaintiffs' and one of Pfizer's prior experts' reports as required by CMO 49.

III. Dr. Roberts Does Not Rely on Dr. Jewell's Re-Analysis in Forming Her Opinions Related to Dosage.

Despite recognizing that Dr. Roberts does not even mention Dr. Jewell or his opinions in her supplemental report, Pfizer nonetheless makes the bold assertion that Dr. Roberts "essentially repeats Dr. Jewell's now-stricken analysis." The Court should take Dr. Roberts's report as it is written, not as Pfizer attempts to re-write it. She neither mentions Dr. Jewell nor cites to any his analyses. The opinions presented in her supplemental report are hers. Clearly many of Plaintiffs' experts agree that all dosages cause diabetes, and the same experts view the NDA and ASCOT data as supportive of their opinions. Many of them discussed the NDA or ASCOT data

in their initial reports. Dr. Jewell does not maintain a monopoly on the opinion that the NDA and ASCOT support causation at the 10mg dose.

Indeed, Dr. Roberts is more than qualified to discuss both the NDA and ASCOT as supporting her opinions. She is a practicing cardiologist and a member of the clinical faculty at the Alpert Medical School of Brown University. She holds the rank of Associate Clinical Professor of Medicine and is the Director of the Women's Cardiac Center at the Miriam Hospital. The Women's Cardiac Center was a site which participated in the AIM-HIGH trial, a clinical trial comparing statin plus placebo to statin plus Niaspan in people with vascular disease and the metabolic syndrome. Dr. Roberts was a principal investigator for that study. She has authored or co-authored articles on statins in peer-reviewed journals and in the lay press. She has also lectured on lipid disorders and their treatment both in the United States and abroad. In her clinical practice, she cares for hundreds of patients with various lipid disorders, patients who have other risk factors for cardiovascular disease, and patients who have established heart disease. She has prescribed statins and other lipid-lowering drugs to patients over several decades and has extensive experience with their efficacy and their adverse effects. She is perfectly competent to analyze and discuss the NDA and ASCOT without the assistance of Dr. Jewell. Pfizer's claim to the contrary is without merit as is Pfizer's claim that Dr. Roberts relied on Dr. Jewell's opinions *at all* in reaching her opinion that Lipitor causes diabetes at all four dosages.

Conclusion

For the reasons stated above, Pfizer's Motion to Strike Supplemental Report of Dr. Roberts should be denied in its entirety.

December 21, 2015

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that, this 21st day of December, 2015, I have electronically filed a copy of the above and foregoing with the Clerk of Court using the ECF system, which sent notification of such filing to counsel of record.

/s/ H. Blair Hahn